K030962

JUL 25 2003

GE Medical Systems

11.0 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

Contact Person:	James P. Raskob GE LUNAR Corporation 726 Heartland Trail Madison, WI 53717
Phone:	(608) 826-7425
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Date:	March 25, 2003
Device/Trade Name:	DPX Series Bravo, Duo Bone Densitometer
Common Name:	Bone Densitometer
Classification Name:	Bone Densitometer 21CFR 892.1170
Predicate Device:	LUNAR PRODIGY 510(k) K982267 LUNAR DPX-Alpha and DPX-L 510(k) K904980

11.1 DESCRIPTION OF THE DEVICE:

The DPX series Bravo, Duo Bone Densitometer provides an estimation of Bone Mineral Density (BMD in g/cm^2) of the spine, femur and forearm. This BMD value can then be compared to a reference population at the sole discretion of the physician.

The DPX Duo has mechanical features to allow use as an exam table when bone densitometry is disabled and the scan arm is rotated and locked parallel to the table.

11.2 SUMMARY OF TECHNICAL CHARACTERISTICS

The DPX series Bravo, Duo Bone Densitometer performs a 90 second scan, with a total skin exposure dose of 2.0 mrem per measurement. The radiation exposure of 2.0 mrem is comparable to the predicate Prodigy and DPX-L bone densitometers.

The BMD spine estimations in vivo provided by the DPX series Bravo, Duo correlate r>0.983 with the Prodigy. The average BMD values obtained in 45 subjects in vivo were very similar with Prodigy and DPX series Bravo, Duo. The average short-term precision (%CV) in vitro was <0.27%. The short-term %CV in vivo was approximately 1.2% for spine, 0.80% for total proximal femur and 1.7% for forearm sub regions BMD. These values are comparable to those shown on currently marketed devices.

11.3 CONCLUSION

The DPX series Bravo, Duo Bone densitometer is substantially equivalent to currently marketed devices. No new safety and effectiveness questions are raised with the DPX series Bravo, Duo Bone Densitometer.

James P. Raskob
Signed

James P. Raskob
Name

Safety and Regulatory Engineering Manager
Title

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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JUL 25 2003

Mr. James P. Raskob
Safety and Regulatory
Engineering Manager
GE Lunar Corporation
General Electric Company
726 Heartland Trail
MADISON WI 53717

Re: K030962
Trade/Device Name: DPX Series Bravo
Duo Bone Densitometer
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone Densitometer
Regulatory Class: II
Product Code: 90 KGI
Dated: July 2, 2003
Received: July 3, 2003

Dear Mr. Raskob:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

3.0 INDICATION FOR USE FORM

- 501(k) Number (if known) K030962
- Device name: DPX Series Bravo, Duo Bone Densitometer
- Indications For Use:

The DPX Series Bravo, Duo Bone Densitometer provides an estimate of BMD at the spine, proximal femur and forearm regions. This BMD value can then be compared to a reference population at the sole discretion of the physician.

The DPX Duo has mechanical features to allow use as an exam table when bone densitometry is disabled and the scan arm is rotated and locked parallel to the table.

The use of the DPX Series Bravo, Duo Bone Densitometer is restricted to prescription use only. The operator's manual for the DPX Series Bravo, Duo system contain the following statement:

"United States Federal Law restricts this device to the sale, distribution, and use by or on the order of a physician."

PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

David A. Lepmann

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030962